

(19)



Europäisches Patentamt

European Patent Office

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(11)

**EP 1 406 690 B1**

(12)

**EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention  
of the grant of the patent:

**30.03.2005 Bulletin 2005/13**

(51) Int Cl.<sup>7</sup>: **A61M 25/00**

(86) International application number:  
**PCT/US2002/020352**

(21) Application number: **02744677.2**

(87) International publication number:  
**WO 2003/008028 (30.01.2003 Gazette 2003/05)**

(22) Date of filing: **27.06.2002**

**(54) LUBRICATING AND GRIPPING DEVICE FOR URINARY CATHETER PACKAGE**

**SCHMIER- UND GREIFVORRICHTUNG FÜR HARNKATHETERVERPACKUNG**

**DISPOSITIF DE LUBRIFICATION ET DE PREHENSION DESTINE A UN EMBALLAGE DE  
CATHETER URINAIRE**

(84) Designated Contracting States:  
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE TR**

(30) Priority: **19.07.2001 US 909223**

(43) Date of publication of application:  
**14.04.2004 Bulletin 2004/16**

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(56) References cited:  
**WO-A-98/06642** **US-A- 4 811 847**  
**US-A- 5 454 798** **US-A- 6 053 905**

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## Description

### Background and Summary of the Invention

[0001] Urinary catheters for draining the bladder through the urethra are commonly packaged in sterile and pre-lubricated condition in flexible containers or pouches. In some cases, the catheters are intended to be fully removed from such containers at the time of catheterization, whereas in others the containers and catheters may remain in communication with the containers then serving as urine-collecting pouches. Reference may be had to U.S. patents 3,854,483 (Powers), 5,226,530 (Golden), 3,934,721 (Juster et al), 6,004,305 (Hursman et al), 5,147,341 (Starke et al) and 6,053,905 (Daignault et al) as illustrative of the art.

[0002] WO-A-98/06642 describes a pre-lubricated urinary catheter and package assembly. The assembly includes a catheter gripping and lubricating device having a housing of a substantially rigid material. Two structures are provided for exerting restraining force onto the catheter. The first structure is a gripping means adapted to be pressed against the catheter when squeezed by the user's fingers. The other structure is an extension control means adapted to permanently apply a restraining force onto the catheter. This restraining force has to be overcome for advancing and applying the catheter by force for pushing the catheter out of the pouch.

[0003] Catheterization commonly involves inserting the distal tip of a catheter (sometimes protected against contamination by an introducer sleeve as disclosed, for example, in 3,854,483 and 4,652,259) into the urethra and then longitudinally collapsing and extending the pouch in an accordion-like manner until the tip reaches the bladder. Such action is illustrated, for example, in 4,062,363 (Bonner). By gripping the remote (proximal) end of the catheter between the walls of the pouch during the pouch-collapsing phase, the catheter is advanced in a distal direction and, conversely, during the pouch-extending phase, the catheter is held against reverse sliding movement by gripping it between the pouch walls near the pouch's distal end. The operation is a two-handed one requiring considerable dexterity to insure that the catheter is advanced during the pouch-collapsing phase and not retracted during the pouch-extending phase.

[0004] Complications may arise that make such a procedure even more difficult. For example, fluid pressure may tend to expel the catheter and require the user to continue gripping the catheter between the walls of the pouch to hold it in place during voiding. Because the catheter is lubricated, immobilizing it by applying a gripping force to the walls of the pouch may require more strength and dexterity than patients can provide, thereby precluding self-catheterization.

[0005] In an effort to reduce such problems, some packages for prelubricated catheters contain gripping devices that may be squeezed to help hold a catheter

against reverse sliding movement (see 6,053,905, 6,004,305 and WO 98/06642). Typically, such gripping devices are designed to engage the side surfaces of a catheter but, since those surfaces are already lubricated, slippage may still readily occur.

[0006] Lubricating and gripping systems used in current catheter packages often have other shortcomings as well. Lubricant gel may not be retained in one area of such a package but may be free to migrate into the urine-collective chamber, causing the walls of the pouch to stick together and make voiding more difficult. Squeezable gripping devices, even if properly fitted onto the tip of a catheter during production, may slip off during storage and transport, requiring a user to refit such a device prior to catheterization. Further, in some constructions, lubricant tends to be unevenly distributed over the surfaces of a catheter, causing patient discomfort and risking possible injury during catheterization.

[0007] This invention therefore concerns an improved catheter gripping and lubricating device according to claim 1 and self-lubricating catheter package according to claim 7 that overcomes or at least greatly reduces the aforementioned defects and disadvantages of current products. More specifically, this invention involves a catheter package in which lubricant (preferably in the form of a gel) is retained in a housing located within the distal end portion of a pouch. Means are provided to insure even distribution of the lubricant over the surfaces of a catheter during a catheterization procedure. The housing includes gripping means which, in contrast to conventional devices, normally holds a catheter against sliding movement and releases that catheter for movement only when squeezing forces are applied by a user's fingers. Since the gripping means automatically restrains sliding movement of the catheter in the absence of such squeezing forces, the device holds the catheter in place during storage and transport, thereby eliminating the possibility that a user might have to reinsert the catheter into the gripping device prior to use. Further, the gripping device easily holds the catheter in place in the urethra during voiding and also eliminates or greatly reduces the possibility of reverse movement of the catheter during the pouch-collapsing and pouch-extending phases of catheterization. The catheter gripping and lubricating device is therefore believed to be considerably more effective in operation and ease of use than existing devices and, when used in combination with a flexible container or pouch, results in a catheter package that is superior to current assemblies.

[0008] Briefly, the catheter gripping and lubricating device includes a deformable and shape-recoverable housing of elastomeric material defining a lubricant chamber. At its distal end, the chamber is substantially closed by an end cap having an axial catheter-receiving passage extending therethrough. The opposite or proximal end of the chamber includes a retention wall that restrains lubricant flow in a proximal direction from the housing. The retention wall is apertured to allow sliding

movement of a catheter into and through the lubricant chamber of the housing.

[0009] Catheter gripping means is located at the proximal end portion of the housing in advance of (i.e., proximal to) the apertured retention wall and lubricant chamber. The gripping means normally grips opposite side surfaces of a catheter to restrain its sliding movement but is deformable upon the application of squeezing force (by a user's fingers applied against the opposite side walls of the housing) to selectively release the catheter for sliding movement. The catheter gripping means includes a pair of deformable clamping members that normally frictionally engage opposite side surfaces of the catheter, such clamping members extending between and being connected to upper and lower walls of the housing so that squeezing forces applied to those walls will cause the clamping members to bow outwardly away from each other and release the catheter for sliding movement.

[0010] The catheter gripping and lubricating device is located within the distal end of a pouch that maintains the catheter in sterile condition prior to use and may advantageously serve as a urine collection pouch during catheterization. Ideally, side surfaces of the guide housing's end cap are heat sealed or otherwise bonded to inside surfaces of the pouch at its distal end. The end cap includes a tubular extension that projects through and beyond the pouch's distal end, and in one preferred embodiment of the invention such extension carries a soft pliant introducer sleeve designed to protect the catheter tip against contamination by non-sterile urethral surfaces immediately adjacent the urethral opening.

[0011] A lubricant, preferably in the form of a lubricant gel, is disposed in the lubricant chamber. The passage of the distal end cap, including the extension of that end cap, is of a diameter sufficiently greater than the outside diameter of the catheter to insure that a thin even coating of lubricant is applied to and remains on the catheter as it is advanced into the urethra. In that connection, it is to be noted that squeezing forces applied to the lubricant housing for purposes of releasing the gripping means also helps to insure that lubricant will be forced into contact with the external surfaces of the catheter as it advances through the lubricant chamber.

[0012] Other features, objects and advantages of the invention will become apparent from the drawings and specification.

### Drawings

#### [0013]

Figure 1 is a top plan view of a catheter package embodying this invention.

Figure 2 is a perspective view showing the catheter gripping and lubricating device, with a catheter extending therethrough, in solid lines; for clarity of il-

lustration, the enclosing pouch is depicted in phantom.

Figure 3 is a longitudinal sectional view of the complete catheter package.

Figure 4 is an enlarged cross sectional view taken along line 4-4 of Figure 3.

Figure 5 is a cross sectional view similar to Figure 4 but showing the housing in an untensioned state prior to insertion of a catheter.

Figure 6 is a sectional view similar to Figure 4 but illustrating deformation of the gripping means by the application of squeezing forces to the housing for purposes of releasing a catheter for sliding movement therethrough.

Figure 7 is a fragmentary perspective view, shown partly in section and partly in phantom, illustrating details of the catheter gripping means.

Figure 8 is a fragmentary perspective view of the distal end of the housing with the catheter gripping means sectioned along its longitudinal vertical mid-plane to further illustrate structural details of the catheter gripping means.

### Detailed Description of Preferred Embodiments

[0014] Referring to the drawings, the numeral 10 generally designates a sterile self-lubricating catheter package comprising a flexible container 11 in the form of a flat, elongate pouch or bag 11 having top and bottom side walls 11a and 11b preferably formed of heat-sealable film. In the illustration given, the pouch is generally rectangular in outline with longitudinal side edges 12, a proximal end 13, and a distal end 14. The pouch may be formed as an extruded tube with proximal end 13 closed by heat seal 13a and distal end 14 sealed by transverse heat seal 14a. The terms "top" and "bottom" are being used here in referring to walls 11a and 11b to facilitate description of the assembly as a whole but, in view of the symmetry of the pouch, it will be understood that these terms are arbitrary and that the pouch may just as easily be placed on a support surface in flipped over condition with 11b constituting the top wall and 11a the bottom wall. Also, while a rectangular configuration is shown, that shape is not considered critical.

[0015] Disposed entirely within the pouch is a urinary catheter 15 and a catheter gripping and lubricating device 16. The catheter may take the form of a standard urinary catheter of tubular shape formed of soft flexible thermoplastic material. One or more openings 17 are provided at its distal end. At its proximal end, the catheter may be provided with a frusto-conical fitting 18 which prevents or restrains extraction of the catheter from the pouch through gripping and lubricating device 16 and, if desired, may also be used as a Luer fitting for attachment to a syringe or other suitable instrument or device (after the pouch has been opened at its proximal end). Alternatively, fitting 18 may be omitted and, if desired, some other fitting (which may or may not operate

as a stop member) may be provided.

**[0016]** The catheter gripping and lubricating device 16 comprises a tubular guide housing 20 having convexly curved upper and lower side walls 21 and 22 merging along longitudinal edges 23 to define a lubricant chamber 24 of greater width than height. The housing includes cap means 25 sealed to walls 21 and 22 at the distal end of the chamber. Lubricant retention means in the form of a proximal wall portion 26 substantially closes off the proximal end of the chamber 24. The proximal end wall portion 26 has a central aperture 27 for slidably receiving catheter tube 15, and distal end cap 25 has a coaxial passage 28 into which the tip of the catheter extends.

**[0017]** As shown in Figure 3, end cap 25 also has a distal extension 25a through which passage 28 continues. Extension 25a is disposed externally of pouch 11, projecting a short distance beyond the pouch's distal end 14. The heat seal 14a that joins the walls of the bag together at the pouch's distal end also joins those walls to the upper and lower surfaces of end cap 25.

**[0018]** Distal extension 25a, passage 28, and the tip of sterile catheter 15 may all be protected against contamination by a removable cap (not shown) covering the extension. Alternatively (or additionally), the catheter package 10 thus described may be sealed within a second pouch or bag (not shown) to maintain the package in sterile condition. In the particular embodiment illustrated in the drawings, a soft elastomeric introducer 30 having a tubular sleeve portion 31 and flange 32 is secured to extension 25. The distal end of the sleeve portion 31 is rounded and closed except for one or more slits 33. As shown in Figure 3, the lumen 34 of the introducer's sleeve portion 31 registers directly with passage 28 of the end cap 25 and its extension 25a. The length of the sleeve portion is such that, upon insertion into the urethra, it will shield the catheter 15 against contact with and contamination by a short stretch of the urethra adjacent the labia.

**[0019]** Use of the introducer 30 is optional. Where provided, its surfaces should be maintained in sterile condition prior to use. Such sterility may be achieved by means of a cap (not shown) removably fitted upon sleeve portion 31, or by locating the entire assembly shown in Figure 3 within a sterile outer wrap (not shown), or both.

**[0020]** The guide housing 20 is deformable and shape-recoverable, being formed an elastomeric material such as silicone rubber or other polymer having similar properties. At its proximal end, located beyond (in a direction proximally to) the apertured wall 26, is a catheter gripping mechanism 40 formed integrally with the housing. The gripping mechanism includes a pair of laterally-spaced clamping members 41 and 42 extending along opposite sides of catheter 15 and normally engaging the catheter with sufficient force to restrain its longitudinal sliding movement through the housing (Figure 4). The clamping members are connected to each other

along their upper and lower limits by upper and lower connecting walls 43 and 44 which slope radially inwardly in a distal direction (Figures 3, 7 and 8) and which in turn are joined to upper and lower walls 21 and 22 by vertical walls 45 and 46 extending along the guide housing's vertical midplane. Since clamping members 41 and 42 are spaced laterally outwardly from that midplane, squeezing forces applied by the fingers to upper and lower walls 21 and 22, in the directions of arrows 47 in Figure 6, cause the clamping members to bow outwardly and release catheter 15. Such action is aided by horizontal connecting walls 48 and 49 which join each of the clamping members to the walls of the housing adjacent longitudinal edges 23. Since the longitudinal edges are urged apart when squeezing forces are applied in the directions of arrows 47, a pulling action (represented by arrows 47a) also takes place to draw the clamping members outwardly into their catheter-releasing positions.

**[0021]** Figures 5-8 illustrate the reason for the self-clamping action of the catheter gripping means. Members 41 and 42 are shown to be planar when in untensioned condition. The spacing between the untensioned clamping members is substantially less than the outside diameter of catheter 15, as well as less than the diameter of aperture 27. Before insertion of catheter, members 41 and 42 therefore appear as shown in Figures 5, 7 and 8, whereas following insertion the clamping members are forced laterally away from each other, as depicted in Figure 4, and, because of the forces of elastic recovery normally exerted by the housing, such members grip and restrain the catheter against sliding movement.

**[0022]** It will be noted that the passage 50 through the gripping means 40 changes substantially when viewed both longitudinally and transversely. When the clamping means is in an undeformed state as shown in Figure 7, the passage 50 terminates at its proximal end in a narrow, vertically elongated rectangular opening 51, and, at its opposite distal end, in circular opening or aperture 27 having a slightly smaller diameter than the outside diameter of the catheter to be extended therethrough. Since the horizontal width of the rectangular opening 51 is less than the diameter of aperture 27, the passage viewed in horizontal section becomes slightly wider in a distal direction. However, when viewed in vertical section (Figure 8), the same passage tapers sharply in a distal direction throughout the transition from rectangular to circular configuration.

**[0023]** Vertical walls 45 and 46, and horizontal walls 48 and 49 all contribute in causing clamping members 41 and 42 to bow outwardly as squeezing forces are applied in the directions shown by arrows 47 in Figure 6. In addition, horizontal walls 48 and 49 act to brace the clamping members 41 and 42 and help to ensure a secure gripping force is applied to the sides of a catheter until such time as the housing is deformed by squeezing force as representative in Figure 6.

[0024] A lubricant 52 is located within chamber 24 of housing 20. The lubricant is a liquid or gel and may be any of a variety of materials commonly used for lubricating urinary catheters. Its viscosity may be varied from that of a readily flowable oil to that of a more viscous semi-liquid, although a lubricant gel is generally preferred. Such a lubricant is preferably, but not necessarily, water soluble.

[0025] As already indicated, the gripping and lubricating device 16 and catheter 15 would be made available to a user in a protective pouch or envelope 11. Catheter 15 extends through lubricant-containing chamber 24 with its tip located in passage 28 of distal end cap 25. At the time of catheterization, a user squeezes the side walls 21 and 22 together to release the catheter for sliding movement as illustrated in Figure 6 and then, with the fingers of the other hand, grips the proximal end portion of the catheter between walls 11a and 11b of the pouch and urges the catheter distally. Such action causes the pouch walls to collapse, producing accordion-like folds, as the pouch's proximal end approaches guide housing 20. The user then relieves the squeezing force applied to the guide housing 20, allowing the housing to return to its clamping condition depicted in Figure 4, and draws the proximal end of the pouch outwardly into its original unfolded condition. The process is repeated until the tip of the catheter has passed through the urethra and reaches the bladder. If the pouch is to be used as a fluid collection device (as shown) urine flows through the catheter into the chamber of the pouch. During a voiding procedure, no squeezing force is applied to guide housing 20, with the result that the guide housing automatically restrains retrograde sliding movement caused by fluid flow and pressure.

[0026] The flowable lubricant 52 contained in chamber 24 is applied to the external surfaces of catheter 15 as that catheter is advanced during a catheterization procedure. It is to be noted that the same squeezing force applied to release the gripping action of members 41 and 42 (Figure 6) also forces the lubricant in chamber 24 into more complete contact with the outer surfaces of the catheter as it is advanced. As shown in Figure 3, passage 28 through end cap 25 and its extension 25a is of sufficiently larger diameter than the outside diameter of the catheter to insure that a thin uniform coating of lubricant will remain on the catheter as it enters a patient's urethra.

[0027] Unlike gripping means sometimes found in other catheter packages, the gripping members 41 and 42 disclosed herein are normally in their catheter-restraining mode and are shifted into releasing positions only when squeezing forces are applied. Effective gripping action is assured because contact is made with unlubricated catheter surfaces, that is, gripping frictional contact occurs with such surfaces well before they reach the lubricant-containing chamber.

[0028] Clamping members 41 and 42 have been shown and described as being vertically oriented and

extending in directions normal to the plane of the generally flat pouch, and such orientation is indeed preferred. However, it is to be noted that alternatively housing 20 might be rotated 90° relative to the plane of the pouch so that clamping members 41 and 42 are generally parallel with that plane and, in such a case, the catheter gripping mechanism would still be operative although such operation would be somewhat less convenient for a user than the operation of the preferred version illustrated.

## Claims

1. A catheter gripping and lubricating device (16) comprising a deformable and shape-recoverable guide housing (20) of elastomeric material having proximal and distal end portions and defining a lubricant chamber (24) therebetween; end cap means (25) at said distal end portion and lubricant retention means (26) at said proximal end portion for retaining lubricant (52) within said chamber (24); said end cap means (25) having a central passage (28) and said lubricant retention means (26) having a coaxial aperture (27) for sliding movement of a catheter (15) therethrough as such catheter (15) is advanced through said lubricant chamber (24) of said housing (20); and catheter gripping means (40) in said proximal end portion of said housing (20); said gripping means (40) including clamping members (41, 42) with opposing surfaces normally spaced closely together for defining a restraining position for automatically frictionally engaging opposite side surfaces of a catheter (15) to restrain sliding movement thereof but being movable into catheter releasing positions when said proximal end portion is squeezed by the user's fingers to cause spreading apart of said opposing surfaces to permit sliding movement of the catheter (15) through said housing (20).
2. The device of claim 1 in which said catheter gripping means (40) is located proximally in relation to said lubricant chamber (24) and said lubricant retention means (26).
3. The device of claim 1 in which said catheter gripping means (40) includes a pair of deformable clamping members (41, 42) normally frictionally engaging opposite side surfaces of said catheter (15); said clamping members (41, 42) extending between and being connected to side walls (21, 22) of said housing (20); whereby, squeezing forces applied to said housing side walls (21, 22) causes said deformable clamping members (41, 42) to bow outwardly and release said catheter (15) for sliding movement relative to said housing.

4. The device of claim 1 wherein said deformable and shape-recoverably guide housing (20) is of generally tubular shape and has convexly curved side walls (21, 22) merging along longitudinally-extending edges to define said lubricant chamber (24). 5
5. The device of claim 4 in which said longitudinally-extending edges of said housing (20) are displaced away from each other when said side walls (21, 22) of said housing (20) are squeezed together, said housing (20) including connecting walls (45, 46, 48, 49) joining mid-portions of said deformable clamping members (41, 42) to said housing (20) along said edges to cause said clamping members (41, 42) to bow outwardly and release said catheter (15) for sliding movement when said upper and lower side walls (21, 22) of said housing are squeezed together. 10
6. The device combination of claim 3 in which said clamping members (41, 42) are each generally planar in untensioned condition. 15
7. A catheter package including a catheter and the device of any one of claims 1 to 6, wherein said device (16) is located within a generally flat pouch (11) having side walls formed of flexible thermoplastic film. 20
8. The package of claim 7 in which a flowable lubricant is disposed in said chamber (24) and a urinary catheter (15) extends into said chamber (24) through said aperture (27) of said lubricant retention means (26). 25
9. The package of claim 8 in which said catheter (15) has a distal tip portion extending into said central passage (28) of said end cap means (25). 30
10. The package of claim 7, wherein said pouch (11) has proximal and distal ends (13, 14) and said distal end portion of said housing (20) is sealed to said pouch (11) between the walls thereof at said pouch's distal end (14). 35
11. The package of claim 10 in which said end cap means (25) includes a tubular extension (25a) projecting through and beyond said pouch (11) at the distal end (14) thereof. 40
12. The package of claims 10 or 11 in which said passage (28) of said end cap means (25) is larger in diameter than the outside diameter of said catheter (15), whereby, lubricant applied to said catheter (15) when the catheter (15) is advanced through said lubricant chamber (24) remains as a lubricant coating on said catheter (15) as said catheter passes through said passage (28). 45

13. The package of claim 11 in which a tubular introducer (30) is mounted on said extension (25a) externally of said pouch (11), said introducer (30) having a distal end wall provided with at least one self-closing slit (33) capable of opening to allow said catheter (15) to be advanced therethrough. 50
14. The package of claim 7 in which said pouch (11) has a distal end portion (14) internally sealed to said distal end portion of said guide housing (20). 55
15. The package of claim 8 in which said flowable lubricant is a lubricant gel.

#### Patentansprüche

1. Kathetergreif- und Schmiereinrichtung (16) mit einem verformbaren und in seine Gestalt zurückkehrenden Führungsgehäuse (20) aus einem elastomeren Material mit proximalen und distalen Endbereichen, wobei eine Schmiermittelkammer (24) dazwischen definiert ist; einer Endkappeneinrichtung (25) am distalen Endbereich und einer das Schmiermittel zurückhaltenden Einrichtung (26) am proximalen Endbereich zum Zurückhalten des Schmiermittels (52) innerhalb der Kammer (24); wobei die Endkappeneinrichtung (25) einen zentralen Durchtritt (28) und die das Schmiermittel zurückhaltende Einrichtung (26) eine koaxiale Öffnung (27) für eine Gleitbewegung eines Katheters (15) aufweisen, wenn ein Katheter (15) durch die Schmiermittelkammer (24) des Gehäuses (20) vorgeschoben wird; und mit einer Kathetergreifeinrichtung (40) im proximalen Endbereich des Gehäuses (20) wobei die Greifeinrichtung (40) Klemmelemente (41, 42) aufweist, deren gegenüberliegende Oberflächen gewöhnlich eng benachbart beabstandet sind, um eine Rückhalteposition zu definieren zum automatischen Eingriff unter Reibung mit gegenüberliegenden Seitenoberflächen eines Katheters (15), um seine Gleitbewegung zu behindern, jedoch in Katheterlösepositionen bewegbar sind, wenn der proximale Endbereich durch die Finger des Benutzers gequetscht wird, um die gegenüberliegenden Oberflächen auseinander zu spreizen, um eine Gleitbewegung des Katheters (15) durch das Gehäuse (20) zu gestatten.
2. Einrichtung nach Anspruch 1, wobei die Kathetergreifeinrichtung (40) proximal bezüglich der Schmiermittelkammer (24) und der Rückhalteeinrichtung (26) für das Schmiermittel angeordnet ist.
3. Einrichtung nach Anspruch 1, wobei die Kathetergreifeinrichtung (40) ein Paar verformbare Klemmelemente (41, 42) enthält, die normalerweise mit gegenüberliegenden Seitenoberflächen des Katheters (15) in Eingriff kommen.

- ters (15) in Reibeingriff stehen; wobei sich die Klemmelemente (41, 42) zwischen den Seitenwänden (21, 22) des Gehäuses (20) erstrecken und mit diesen verbunden sind; wodurch auf die Seitenwände (21, 22) des Gehäuses aufgebrachte Quetschkräfte bewirken, dass sich die verformbaren Klemmelemente (41, 42) nach außen biegen und den Katheter (15) für eine Gleitbewegung relativ zum Gehäuse freigeben.
4. Einrichtung nach Anspruch 1, wobei das verformbare und in seine Gestalt zurückbringbare Führungsgehäuse (20) im Wesentliche rohrförmig ausgebildet ist und konvex gekrümmte Seitenwände (21, 22) aufweist, die entlang sich in Längsrichtung erstreckender Kanten zusammenlaufen, um die Schmiermittelkammer (24) zu definieren.
5. Einrichtungen nach Anspruch 4, wobei die sich in Längsrichtungen erstreckenden Kanten des Gehäuses (20) voneinander wegbewegt werden, wenn die Seitenwände (21, 22) des Gehäuses (20) zusammengequetscht werden; wobei das Gehäuse (20) Verbindungswände (45, 46, 48, 49) enthält, die Mittelbereiche der verformbaren Klemmelemente (41, 42) entlang der Kanten mit dem Gehäuse (20) verbinden, um zu bewirken, dass sich die Klemmelemente (41, 42) nach außen bewegen und den Katheter (15) für eine Gleitbewegung freigeben, wenn die oberen und unteren Seitenwände (21, 22) des Gehäuses zusammengequetscht werden.
6. Einrichtungskombination des Anspruchs 3 wobei die Klemmelemente (41, 42) in einem ungespannten Zustand jeweils im Wesentlichen eben sind.
7. Katheterverpackung mit einem Katheter und der Einrichtung nach einem der Ansprüche 1 bis 6, wobei die Einrichtung (16) innerhalb eines im Wesentlichen flachen Beutels (11) angeordnet ist, der aus einem flexiblen thermoplastischen Film gefertigte Seitenwände aufweist.
8. Verpackung nach Anspruch 7, wobei das fließfähige Schmiermittel in der Kammer (24) angeordnet ist und sich ein Hamkatheter (15) in die Kammer (24) durch die Öffnung (27) der Rückhalteeinrichtung (26) für das Schmiermittel erstreckt.
9. Verpackung nach Anspruch 8, wobei der Katheter (15) einen distalen Spitzenbereich aufweist, der sich in den zentralen Durchtritt (28) der Endkappeneinrichtung (25) erstreckt.
10. Verpackung nach Anspruch 7, wobei der Beutel (10) proximale und distale Enden (13, 14) aufweist und der distale Endbereich des Gehäuses (20) mit dem Beutel (11) zwischen dessen Wänden an dem
- distalen Ende (14) des Beutels versiegelt ist.
11. Verpackung nach Anspruch 10, wobei die Endkappeneinrichtung in (25) eine rohrförmige Verlängerung (25a) aufweist, die sich durch und über den Beutel (11) an seinem distalen Ende (14) erstreckt.
12. Verpackung nach Anspruch 10 oder 11, wobei der Durchtritt (28) der Endkappeneinrichtung (25) einen größeren Durchmesser aufweist als der Außendurchmesser des Katheters (15), wodurch das Schmiermittel, das auf den Katheter (15) aufgebracht wurde, wenn der Katheter (15) durch die Schmiermittelkammer (24) vorgeschoben wird, als Schmiermittelbeschichtung auf dem Katheter (15) bleibt, wenn der Katheter durch den Durchtritt (28) hindurchtritt.
13. Verpackung nach Anspruch 11, wobei eine rohrförmige Einsetzeinrichtung 30 an der Verlängerung (25a) außerhalb des Beutels (11) montiert ist, wobei die Einsetzeinrichtung (30) eine distale Endwand aufweist, die mit mindestens einem selbstschließenden Schlitz (33) versehen ist, der geöffnet werden kann, damit der Katheter (15) hindurchgeschoben werden kann.
14. Verpackung nach Anspruch 7, wobei der Beutel (11) einen distalen Endbereich (14) aufweist, der innen mit dem distalen Endbereich des Führungsgehäuses (20) versiegelt ist.
15. Verpackung nach Anspruch 8, wobei das fließfähige Schmiermittel ein Schmiermittelgel ist.

## Revendications

1. Dispositif de préhension et de lubrification pour cathéter (16) comprenant un logement guide déformable pouvant récupérer sa forme (20) en matériau élastomère ayant des parties extrêmes proximale et distale et définissant entre elles une chambre lubrifiante (24), un moyen formant capsule d'extrémité (25) au niveau de la partie distale d'extrémité et un moyen de rétention de lubrifiant (26) au niveau de la partie proximale pour retenir du lubrifiant (52) à l'intérieur de la chambre (24), le moyen formant capsule d'extrémité (25) ayant un passage central (28) et le moyen de rétention de lubrifiant (26) comportant une ouverture coaxiale (27) afin de permettre un mouvement glissant d'un cathéter (15) à travers laquelle le cathéter en tant que tel (15) est avancé à l'intérieur de la chambre lubrifiante (24) du logement (20), un moyen de préhension du cathéter (40) dans la partie proximale d'extrémité du logement (20), le moyen de préhension comprenant des pièces de bridage (41, 42) à surfaces opposées

- normalement espacées proches l'une de l'autre pour définir une position de maintien permettant automatiquement une prise par frottement des surfaces latérales opposées d'un cathéter (15) afin de restreindre le mouvement de glissement de ce dernier mais pouvant être déplacées dans des positions de libération du cathéter lorsque la partie proximale d'extrémité est pressée par les doigts de l'utilisateur pour provoquer un écartement des surfaces opposées permettant le mouvement glissant du cathéter (15) à travers le logement (20).
2. Dispositif selon la revendication 1, dans lequel le moyen de préhension de cathéter (40) est situé de manière proximale par rapport à la chambre lubrifiante (24) et au moyen de rétention de lubrifiant (26).
  3. Dispositif selon la revendication 1, dans lequel le moyen de préhension de cathéter (40) comprend une paire de pièces de bridage déformables (41, 42) mettant normalement en prise par frottement des surfaces latérales opposées du cathéter (15), les pièces de bridage (41, 42) s'étendant entre des parois latérales (21, 22) du logement (20), et étant raccordées à celles-ci, de sorte que des forces de pression appliquées sur les parois latérales du logement (21, 22) font plier vers l'extérieur les pièces de serrage déformables (41, 42) et relâcher le cathéter (15), lui permettant un mouvement de glissement par rapport au logement.
  4. Dispositif selon la revendication 1, dans lequel le logement guide déformable pouvant récupérer sa forme (20) est de forme globalement tubulaire et pourvu de parois latérales courbes convexes (21, 22) se rejoignant le long d'arêtes s'étendant longitudinalement pour définir la chambre lubrifiante (24).
  5. Dispositif selon la revendication 4, dans lequel les arêtes, s'étendant longitudinalement, du logement (20) sont déplacés par éloignement mutuel lorsque les parois latérales (21, 22) du logement (20) sont pressées mutuellement, le logement (20) comprenant des parois de raccordement (45, 46, 48, 49) reliant des moitiés des pièces de bridage déformables (41, 42) au logement (20) le long des arêtes pour faire courber vers l'extérieur les pièces de bridage (41, 42) et libérer le cathéter (15), lui permettant un mouvement glissant lorsque les parois latérales supérieures et inférieures (21, 22) du logement sont pressées ensemble.
  6. Dispositif combiné selon la revendication 3, dans lequel les pièces de bridage (41, 42) sont chacune globalement planes à l'état non tendu.
  7. Dispositif à cathéter comprenant un cathéter et le dispositif selon l'une quelconque des revendications 1 à 6, dans lequel le dispositif (16) est situé à l'intérieur d'une poche globalement plate (11) ayant des parois latérales formées par un film souple thermoplastique.
  8. Dispositif selon la revendication 7, dans lequel un lubrifiant fluide est disposé dans la chambre (24) et un cathéter urinaire (15) s'étend dans la chambre (24) à travers l'ouverture (27) du moyen de retenue de lubrifiant (26).
  9. Dispositif selon la revendication 8, dans lequel le cathéter (15) comprend une partie distale de pointe s'étendant dans le passage central (28) du moyen formant capsule d'extrémité (25).
  10. Dispositif selon la revendication 7, dans lequel la poche (11) comprend des extrémités proximale et distale (13, 14) et la partie distale extrême du logement (20) étant scellée à la poche (11) entre les parois de la poche au niveau de l'extrémité distale de la poche (14).
  11. Dispositif selon la revendication 10, dans lequel le moyen formant capsule d'extrémité (25) comprend une extension tubulaire (25a) avançant à travers et au-delà de la poche (11) au niveau de l'extrémité distale (14) de cette dernière.
  12. Dispositif selon les revendications 10 ou 11, dans lequel le passage (28) du moyen formant capsule d'extrémité (25) est de diamètre plus grand que le diamètre extérieur du cathéter (15), de sorte que le lubrifiant appliqué au cathéter (15), lorsque le cathéter est avancé à travers le logement lubrifiant (24), reste comme revêtement lubrifiant sur le cathéter (15) lorsque le cathéter traverse le passage (28).
  13. Dispositif selon la revendication 11, dans lequel un introducteur tubulaire (30) est monté sur l'extension (25a) de manière externe à la poche (11), l'introducteur (30) ayant une paroi distale d'extrémité pourvue d'au moins une fente à auto-obturation (33) apte à s'ouvrir pour permettre au cathéter (15) d'être avancé à travers cette dernière.
  14. Dispositif selon la revendication 7, dans lequel la poche (11) comprend une partie distale d'extrémité (14) scellée en interne à la partie distale d'extrémité du logement de guidage (20).
  15. Dispositif selon la revendication 8, dans lequel le lubrifiant fluide est un gel lubrifiant.



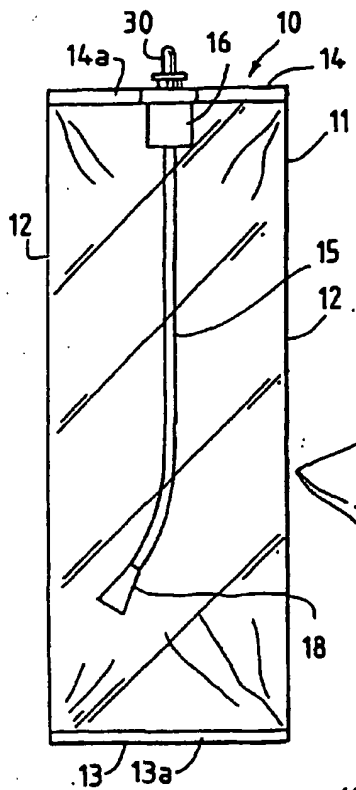


FIG. 1

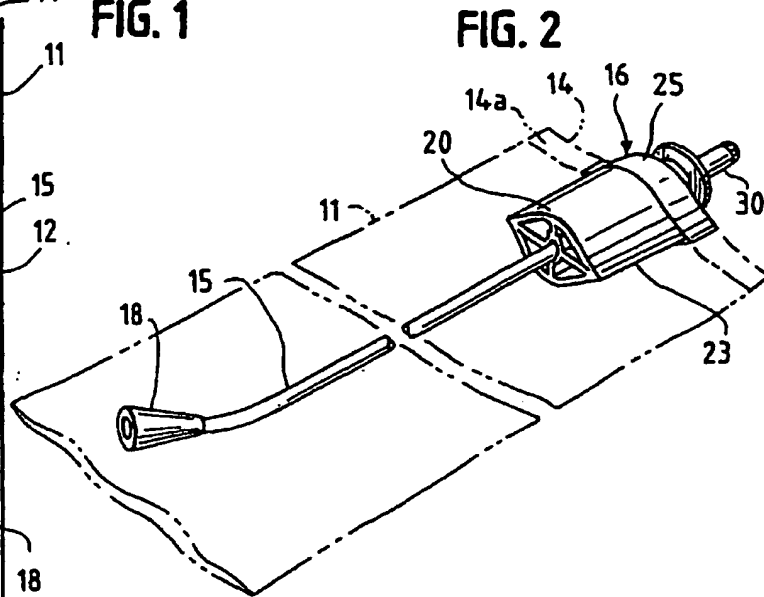


FIG. 2

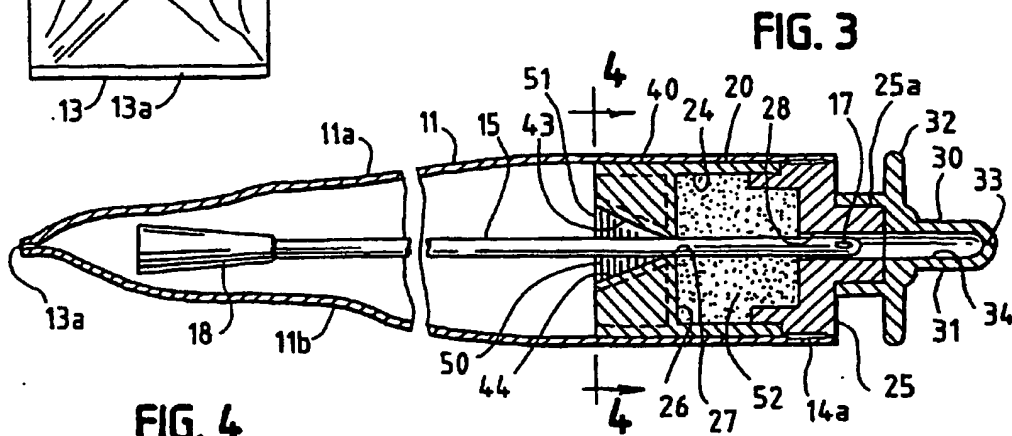


FIG. 3

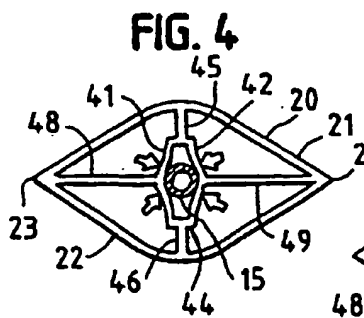


FIG. 4

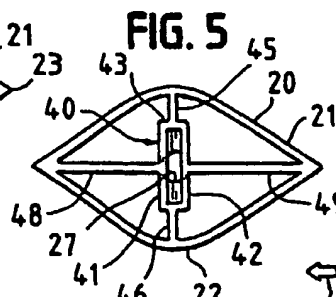


FIG. 5

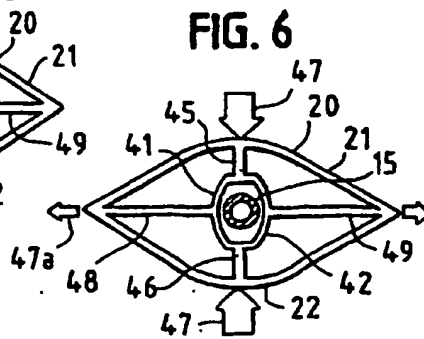


FIG. 6

FIG. 7

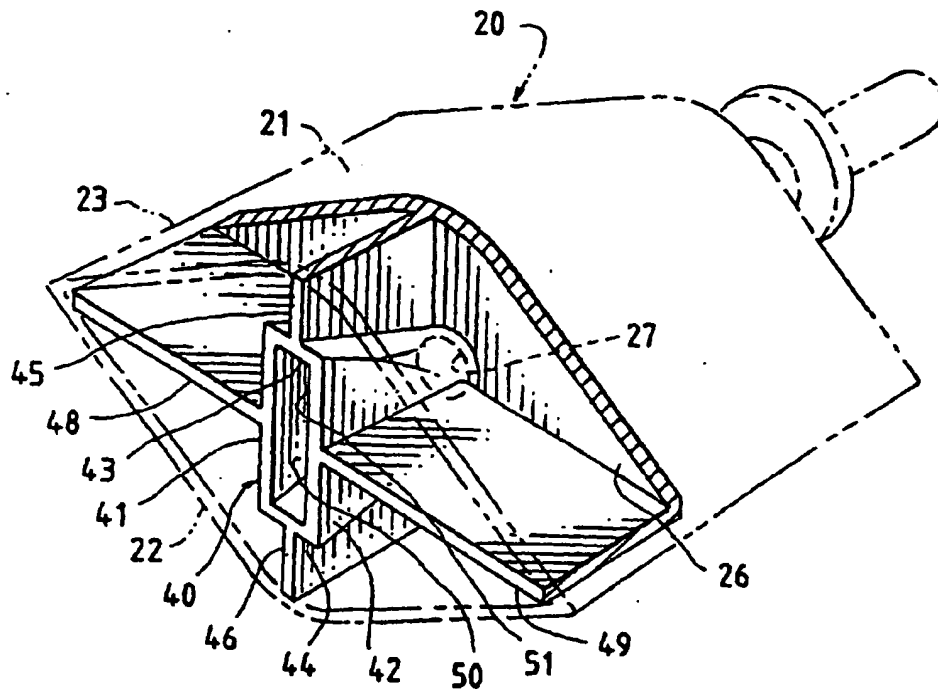


FIG. 8

